報告書

医薬品医療機器レギュラトリーサイエンス
Pharmaceutical and Medical Device Regulatory Science
Vol. 50, No. 5, 286～294 (2019)

高速液体クロマトグラフィー－質量分析計(HPLC-MS/MS)を用いたゲンタマイシン硫酸塩の品質評価法の検討*2

福田 菜々子，坂井 愛，高橋 知里，前川 京子*1, #

Quality Evaluation of Gentamicin Sulfates by Hydrophilic Interaction Chromatography with Tandem Mass Spectrometry

Nanako FUKUDA, Megumi SAKAI, Chisato TAKAHASHI and Keiko MAEKAWA*1, #

Summary

Gentamicin sulfates (GM) are a multi-component mixture of broad-spectrum water-soluble aminoglycoside antibiotics widely used for the treatment of various infections caused by both Gram-negative and Gram-positive bacteria. There are three major components, C1, C1a and C2, together with numerous minor components, including C2a, C2b, garamine and sisomicin. In the Japanese Pharmacopoeia (JP), the antimicrobial potency of GM is determined by microbial assay, while the content ratio and purity of the active components are evaluated by thin-layer chromatography. The traditional assay is based on the antimicrobial activities of all the components, including major and minor components, as well as impurities, making it difficult to achieve good specificity, accuracy and precision. Therefore, besides microbial assay, the quality of GM should be evaluated by physicochemical methods such as chromatographic analysis for each component. In this study, we aimed to apply high-performance liquid chromatography-tandem mass spectrometry (HPLC/MS/MS) to develop quality-control procedures applicable to tests for content ratio and purity of the active components and quantitative assay, meeting the requirements of the GM monograph in JP. GM components and impurities were separated by hydrophilic interaction liquid chromatography (HILIC), and MS analysis was performed by means of selective reaction monitoring (SRM). The developed analytical procedure is suitable for routine quality control of GM.

Key words

Gentamicin, Quality control, Hydrophilic interaction liquid chromatography, Mass spectrometry

本誌掲載記事の無断転載・翻訳を禁止します．また，無断複写・複製は著作権法上の例外を除き禁止されています．